Claims

1. Levalbuterol L-tartrate.

2. Levalbuterol L-tartrate as claimed in Claim 1, which is in crystalline form.

3. Levalbuterol L-tartrate as claimed in Claim 2, containing from 0.3 to 0.7% ethanol.

4. Levalbuterol L-tartrate as claimed in Claim 2, which is in micronized form.

5. Levalbuterol L-tartrate as claimed in Claim 4, which is in the form of needle-like particles.

6. A pharmaceutical composition, which comprises levalbuterol L-tartrate as claimed in Claim 1, together with a pharmaceutically acceptable carrier.

7. A pharmaceutical composition as claimed in Claim 6, which is an aerosol formulation adapted for administration using a metered dose inhaler, the aerosol formulation comprising levalbuterol L-tartrate in crystalline form and a propellant.

8. A pharmaceutical composition as claimed in Claim 7, in which the propellant is 1,1,1,2-tetrafluoroethane.

9. A pharmaceutical composition as claimed in Claim 7, which further comprises a surfactant.

10. A pharmaceutical composition as claimed in Claim 7, which further comprises a co-solvent.

11. A pharmaceutical composition as claimed in Claim 10, in which the co-solvent is ethanol.

12. An aerosol formulation adapted for administration using a metered dose inhaler, the aerosol formulation comprising levalbuterol L-tartrate crystals in the form of micronized, needle-like particles, and a propellant.

13. An aerosol formulation as claimed in Claim 12, in which the propellant is 1,1,1,2-tetrafluoroethane.

14. An aerosol formulation as claimed in Claim 13, which further comprises from 2 to 6% by weight of ethanol as a co-solvent.

15. A metered dose inhaler comprising a canister containing an aerosol formulation as defined in Claim 7, a metering valve and a valve stem.

16. A metered dose inhaler comprising a canister containing an aerosol formulation as defined in Claim 12, a metering valve and a valve stem.

17. A pharmaceutical composition as claimed in Claim 6, which is adapted for administration using a dry powder inhaler or insufflator.

18. A process for the preparation of levalbuterol L-tartrate crystals, which comprises combining a solution of levalbuterol with a solution of L-tartaric acid and recovering levalbuterol L-tartrate crystals.

19. A process as claimed in Claim 18, in which the solvent in each solution comprises ethanol.

20. A process as claimed in Claim 18, in which the crystallization conditions are selected so as to provide crystals having a length of 10 to 50 microns and a width of 0.2 to 4 microns.

21. A process as claimed in Claim 18, in which the levalbuterol L-tartrate has been prepared by hydrogenating R-benzylalbuterol in the presence of palladium on carbon.

22. A process as claimed in Claim 21, in which the hydrogenation has been conducted under conditions selected to effect conversion of at least 99.9% of the R-benzylalbuterol without over reduction of other functional groups.

23. A process as claimed in Claim 18, in which the crystals are dried and micronized, the crystallization and drying conditions being selected so as to afford needle-like particles after micronization.

24. A process for the preparation of levalbuterol L-tartrate crystals, which comprises combining a solution of levalbuterol with a solution of L-tartaric acid, recovering levalbuterol L-tartrate crystals, and then drying and micronizing the recovered crystals, the crystallization and drying conditions being selected so as to afford needle-like particles after micronization.

25. Levalbuterol L-tartrate crystals whenever obtained by the process of Claim 18.

26. Levalbuterol L-tartrate crystals whenever obtained by the process of Claim 24.

27. A method of effecting bronchodilation in a patient in need of treatment, which comprises administering to said patient an effective amount of levalbuterol L-tartrate.

28. A method as claimed in Claim 27, in which micronized crystals of levalbuterol L-tartrate are administered by inhalation using a metered dose inhaler.

29. A method as claimed in Claim 28, in which the micronized crystals of levalbuterol L-tartrate are in the form of needle-like particles.